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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appln. No. : 10/749,046 Confirmation No. 7407

Applicant : William J. Boyle et al.

Filed : December 29, 2003

Art Unit : 3762

Examiner : Moulton, Elizabeth Rose

Title : EMBOLIC PROTECTION DEVICES

Docket No.: : ACSES-66147 (G1738USC1)

Customer No. : 24201 July 17, 2009

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

RESPONSE TO NON-COMPLIANT NOTICE

Dear Sir:

This is in response to the Notice of Non-Compliant Appeal Brief dated July 10, 2009.

This Appeal Brief is being filed pursuant to the Notice of Appeal filed on September 15, 2008 and the Notice of Panel Decision from Pre-Appeal Brief dated May 21, 2009. This Appeal Brief is being filed within one (1) month of the date of the Notice of Panel Decision from Pre-Appeal Brief Review.

INTRODUCTION

The present invention relates to a filter element used to help in the loading and retrieval of embolic debris generated, for example, when a stenting procedure is being performed in an artery. The filter element includes a central region having an inlet opening and a storage reservoir for capturing the embolic debris. The central region includes a plurality of openings adapted to allow blood to flow therethrough but small enough to capture embolic debris larger than the size of the openings to contain the debris within the reservoir. The filter element includes a filter edge integral with a central region and also has an inlet opening. The claimed filter element is directed to the flexible membrane used to capture and collect embolic material entrained in body fluids. For this reason, all of the claims contain the recitation that the central region and filter edge are made from a filter membrane.

In use, the filter element is adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the **filter edge** and thereafter over the central region to move at least a portion of the filter element into the restraining sheath. The filter edge is configured similar to a crown, with a pattern of staggered alternation peaks and valleys that allow the **filter edge** to be incrementally introduced into the restraining sheath, thus preventing the filter membrane from entering the sheath all at once. Each valley region has a particular "depth" and each peak region has a particular "height" with at least two peak regions have different heights. As the filter membrane is being loaded or retrieved, the longer peaks of the filter edge would enter the restraining sheath first and the shorter peaks would enter the sheath, accordingly, later to prevent bunching of the filter edge.

The present application, U.S. Serial No. 10/749,046, was filed on December 29, 2003 and is a continuation application of Serial No. 09/476,159 filed on December 30, 1999, which is now U.S. Patent No. 6,695,813.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, WILLIAM J. BOYLE, DAVID H. BURKETT, ANDY E. DENISON, BENJAMIN C. HUTER, SCOTT J. HUTER, ARKADY KOKISH, KENT B. STALKER, CHICHENG WANG and JOHN D. WHITFIELD to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on May 15, 2000, which was recorded by the U.S. Patent Office on May 19, 2000 beginning at Reel 010835, Frame 0835.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that it is believed there are no such appeals or interferences known to the Appellant.

III. STATUS OF CLAIMS

The status of the claims in this application is:

A. Total Number of Claims in the Application

The pending claims in the application are: Claims 94-116.

Claims 1-93 have been canceled.

B. Status of All Claims on Appeal

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent").

C. Claims on Appeals

The claims on appeal are each of pending claims 94-116. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

On September 15, 2008, the Examiner issued a final Office Action maintaining the §103 rejections of the pending claims. The finally rejected claims attached to this brief are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 94 to 113 are directed to the filter element which constitutes the filter membrane only. Claims 114-116 are directed to the combination of a frame assembly and a filter element made from a filter membrane.

Independent Claim 94

Independent claim 94 is supported in the drawings and specification as follows:

94. (Previously Presented) A filter element (page 40, lines 12-14; FIGS. 41 & 42; #570), for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42;

576) adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir; and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 & 42; #578) and valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580) which prevent the filter edge from entering into the restraining sheath all at one time, wherein each valley region has a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42) and at least two peak regions have different heights and the central region and filter edge are made from a filter membrane.

Independent Claim 101

Independent claim 101 is supported by the drawings and specification as follows:

101. (Previously Presented) A filter element page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into a body vessel, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42; # 576); and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to

move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 & 42; #578) and valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580), wherein each valley region has a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42), at least two peak region having different heights and each valley region has a round configuration which reduces stress concentration at the valley region and the central region and filter edge are made from a filter membrane.

Independent Claim 105

Independent claim 105 is supported by the drawings and specification as follows:

105. (Previously Presented) A filter element page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into a body vessel, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42; # 576); and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by initially drawing the filter edge into the catheter and thereafter the central region to move at least a portion of the filter element into the catheter, the filter edge having a sinusoidal pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 & 42; #578) and

valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580), wherein the filter element can be drawn into the catheter and the valley regions are staggered so that no two valley regions enter the catheter at the same time and the central region and filter edge are made from a filter membrane.

Independent Claim 114

Independent claim 114 is supported by the drawings and specification as follows:

114. (Previously Presented) A filter assembly page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a frame assembly made from a self-expanding material and having a plurality of longitudinally extending struts that move between a collapsed position and an expanded position; and

a filter element made from a filter membrane attached to the frame assembly, the filter element having a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) with an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42; # 576) adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir, and a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 & 42; #578) and valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580), each valley region having a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42) and at least two peak regions having different heights.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the final Office Action dated September 15, 2008, the claims were rejected as follows:

GROUND I

Independent claims 94, 101, 105 and 114, along with their dependent claims, were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent (Exhibit 2) in view of the Gelbfish patent (Exhibit 3).

GROUND II

Dependent claims 115 and 116 were rejected under 35 U.S.C. § 103(a), however, these claims recite a specific frame assembly which is lacking in both the Broome patent and the Gelbfish patent.

VII. ARGUMENT

GROUND I

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Gelbfish patent

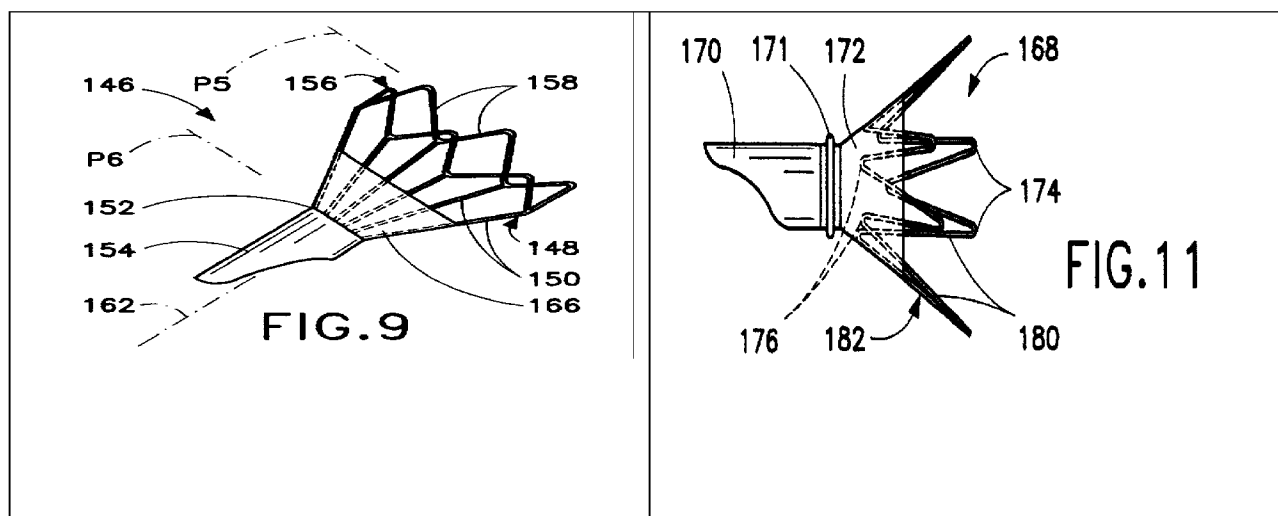
The Examiner takes the position that the Gelbfish patent teaches an embolic filter with a sinusoidal configuration with valleys and peaks of different depths. Appellants strongly disagree with the Examiner characterization of the Gelbfish patent since this patent merely discloses a **frame wire component 156** formed in a zig-zag pattern (Figure 10), not a filter element **made from a filter membrane** as recited in **all** of the pending claims. The presently defined invention is specifically directed to the membrane portion of the embolic protection device which has a plurality of openings adapted to allow blood to flow therethrough but to capture embolic debris larger than the size of the openings and contain the debris within a

storage reservoir formed from the membrane. The membrane shown in the Gelbfish patent does not perform this function, but rather, simply acts as a **solid barrier** to direct blood flow and embolic material into a catheter used to capture the embolic material. A single, large opening, adjacent to this continuous web or film 166 and membrane 172, is used in the Gelbfish patent to direct blood flow into a debris removal instrument that is used to draw fluid and collected material out of the patient utilizing suction. This single opening of the Gelbfish membrane does not capture embolic debris larger than the size of the opening and contain the debris within a storage reservoir formed from the membrane, as is recited in all of the claims. If the embolic material was larger than this single opening, then the debris removal device of Gelbfish would simply get clogged.

The web or film 166 and membrane 172 of the Gelbfish device lack a plurality of perfusion openings. In fact, the Gelbfish patent actually teaches away from the use of perfusions openings in the web or film 166/ membrane 172 since the web or membrane is designed to enhance "the transmission of suction forces during a debris removal operation" (see column 11, lines 66-67 of the Gelbfish patent). Therefore, there are no perfusion openings in this "web or film 166" and "membrane 172" since this membrane must remain liquid impermeable in order to enhance the transmission of suction forces. Multiple openings in the Gelbfish membrane would inhibit the development of needed suction forces. Therefore, the use of a plurality of perfusion openings in the Gelbfish membrane would thwart the ability of the Gelbfish device to capture embolic material and create a suction that is needed to remove both the blood and embolic debris. Therefore, one skilled in the art would simply not look to the Gelbfish patent in solving the problems solved by the currently claimed invention since the Gelbfish membrane is used simply as a solid barrier to direct blood flow into another catheter that collects any embolic

material entrained in the blood. Accordingly, the Gelbfish patent fails to disclose the filter element of the present claimed invention.

The position taken by the Examiner, namely, that "Gelbfish teaches an embolic filter with an edge of a sinusoidal configuration with valleys and peaks of different depths" only relates to the **wire frame** that supports the "web or film 166" or "membrane 172." The web 166 and membrane 172 in the Gelbfish patent are all shown as components having a **straight leading edge** and lack a plurality of with openings. Figures 9 and 11 of the Gelbfish patent are reproduced below:



All of the webs or membranes disclosed in the Gelbfish patent have straight edges which are clearly shown in these figures above. Moreover, the Gelbfish does not teach that the web or membrane can be formed with the wire pattern shown in Figure 10. Rather, the Gelbfish patent states the following at column 11, lines 64-66:

Filter body 148 is provided with a web or film 166 which renders the filter body liquid impermeable at least at its downstream side. Web or film 166 could be made long enough to cover or envelope prongs 150 and zig-zag element 156.

Therefore, the Gelbfish patent does not teach a filter membrane or web that has an edge configured in the shape shown in Figure 10. Rather, the web or

membrane is simply extended upward with a linear edge as shown to cover the frame wire as is depicted in Figure 11 above.

Appellant submit that the Broome patent fails to disclose the structure of the pending claims as has been admitted by the Examiner in previous Office Actions. Appellant believes that the Examiner has simply used the claims as a roadmap in an attempt to reconstruct the presently claimed invention. The Gelbfish patent clearly fails to teach the use of a filter membrane that includes a filter edge having peaks and valleys of varying heights and depths. While it may use a wire edge in its support structure to avoid having the support frame enter into the coupling sleeve 154 at the same time, it is noted that the entire filter web 116 is drawn **proximally into the coupling sleeve 154** at the same time. Figures 3A and 3D of the Gelbfish patent show how a rod or wire 42 is used to retract the support frame and filter web **proximally into the tubular member or sleeve 26/154**. Therefore, there is no need for the filter web/membrane used in the Gelbfish patent to include an edge with a staggered sinusoidal pattern. Accordingly, the Gelbfish patent discloses only a filter web with a straight leading edge. Moreover, the web/membrane of the Gelbfish device is simply used as a solid, but flexible, **funnel** for directing debris into the lumen of a catheter. Given this function, along with Gelbfish's teaching of the use of a straight edge web/membrane, there appears to be no reasonable reason why one skilled in the art would combine the Daniel patent with the Gelbfish patent in the first place, unless of course, one was simply attempting to reconstruct the device using the claims as a roadmap. These are the reasons why Appellant believes that the Examiner has simply used the claims to piece together unrelated devices in order to reject the pending claims.

GROUND II

Claim 115 requires each strut of the frame assembly to have a proximal end and a distal end, the proximal ends of the struts being attached to a proximal collar and the distal ends being attached to a distal collar. Appellant believe that this particular structure is not shown in the Broome patent or Gelbfish patent. The Examiner has taken the position that the element referred to as the mouth 28 of the frame 24 in the Broome patent constitutes a collar. Claim 116 requires each peak region of the filter element to be attached to a **strut** of the frame assembly. Claims 115 and 116 are directed to the embodiment disclosed in FIG. 41. Since the Examiner has taken the position that the mouth 28 constitutes one of the **collars**, the mouth 28 cannot constitute a strut of the frame assembly. The Broome patent clearly shows the filter element attached to the mouth 28 or collar, as the Examiner has interpreted the Broome patent. Therefore, the filter 22 of the Broome patent would not be considered attached to a strut of the frame assembly, as recited in claim 116, but rather, is attached to this "collar 28." The Examiner apparently has taken the position that the filter element is **indirectly** attached to the struts since the collar 28 is attached to the struts. However, Appellant believes that the Examiner's position is not a reasonable interpretation of the Broome patent. The Gelbfish patent also lacks the particular structure recited in claims 115 and 116. Accordingly, the combination of the Gelbfish patent with the Broome patent fails to disclose the particular structure recited in claim 116.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

NONE

XI. CONCLUSION

Appellant submits that there is no believes that the pending claims can be passed to issue as these claims were improperly rejected by the Examiner.

The filing fee of \$510.00 was paid on May 21, 2009 with the Pre-Appeal brief. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

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